Suprarenal graft fixation in endovascular abdominal aortic aneurysm repair is associated with a decrease in renal function

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Introduction: **Suprarenal endograft fixation is routinely used in the endovascular repair of abdominal aortic aneurysms (EVAR) to enhance proximal endograft attachment but can be associated with an adverse outcome in renal function. This prospective study assessed the effect of suprarenal fixation on serum creatinine concentration and estimated glomerular filtration rate (eGFR), calculated by the Modified Diet in Renal Disease equation, 12 months after elective EVAR.**
Methods: **Patients undergoing elective EVAR were divided into suprarenal vs infrarenal fixation groups matched for age, sex, smoking, and aneurysm diameter. Serum creatinine and eGFR were measured at baseline, 6, and 12 months.**
Results: **Included were 92 patients (two women) with a mean age of 71 ± 7 years, with 46 in each group. No device-related complications were noted. Serum creatinine did not differ significantly between groups at 6 ($P = .24$) or 12 ($P = .08$) months but significantly increased in the suprarenal group at 12 months (1.08 ± 0.36 to 1.16 ± 0.36 mg/dL; $P < .001$) vs baseline. The eGFR (mL/min/1.73 m^2) did not differ significantly at baseline between the suprarenal (85 ± 27) and infrarenal (80 ± 28; $P = .33$) groups or at 6 months (88 ± 29 vs 77 ± 24, respectively; $P = .07$). At 12 months, the suprarenal group had a lower eGFR (73 ± 23) than the infrarenal group (84 ± 26; $P = .027$). The eGFR at 12 months showed a significant decrease in the suprarenal (80 ± 28 to 73 ± 23; $P < .001$) but not in the infrarenal group (85 ± 27 to 84 ± 26; $P = .48$). The drop in eGFR differed significantly at 12 months in the infrarenal vs the suprarenal (0.82 vs −6.94; $P < .001$) group. No patient progressed to end-stage renal disease or disclosed a drop in eGFR > 30%.**
Conclusions: **In contrast to previous studies, this study suggests that suprarenal endograft fixation in elective EVAR is associated with a drop in eGFR at 12 months. (J Vasc Surg 2012;56:594-600.)**

Abdominal aortic aneurysm (AAA) constitutes a significant health problem, present in 5% to 10% of men aged >65 years.[1] Endovascular AAA repair (EVAR) is now used in routine clinical practice, and outcomes have proven similar or even superior to traditional open repair.[2] The proximal fixation of the stent grafts deployed in the aorta during EVAR is of crucial importance to avoid device-related complications such as migration and endoleak.[3,4] Suprarenal fixation of the aortic stent grafts has been developed for the purpose of preventing stent graft migration or endoleak by enhancing the hemostatic seal at the proximal aortic neck (cephalad to the aneurysm). Devices with suprarenal fixation, usually in the form of suprarenal bare stents, are typically used to treat aneurysms with short or complicated proximal necks; midterm results are comparable with infrarenal fixation devices.[5-8] The presence of bare stents or barbs above the orifice of the renal arteries has led to the assumption that the implantation of such a device could be associated with a decrease in renal function or complications such as renal artery occlusion, thrombosis, or dissection.[9-12]

Various studies in recent years have examined the effects of suprarenal vs infrarenal stent grant fixation during elective EVAR on renal function, largely suggesting no differences between the two practices, at least in the short-term. Most of these were retrospective cohort studies,[13-17] some were retrospective analyses based on prospectively collected data,[9,18] and fewer followed a prospective cohort design.[19,20] Most of these series had a follow-up of up to 1

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Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
0741-5214/$36.00

doi:10.1016/j.jvs.2012.01.078

year. Some studies included creatinine clearance (based on the Cockroft-Gault formula) instead of simple serum creatinine measurements for renal function evaluation.[15,19,20] However, no study so far has compared carefully balanced groups of patients or examined renal function with the use of the estimated glomerular filtration rate (eGFR),[21] which is currently widely used in clinical practice as the best simple surrogate measure of renal function. The aim of the present prospective, controlled study was to examine the 6- and 12-month effects on renal function of suprarenal vs infrarenal proximal stent graft fixation in elective EVAR.

METHODS

Study design and population. This study followed a predefined nested case-control design, with both cases and controls deriving from one prospectively assembled cohort of patients. This original cohort included patients undergoing elective EVAR of an infrarenal AAA between January 2008 and April 2010 in our tertiary referral center, who provided written informed consent for their information to be recorded in a prospective registry and met the inclusion criteria of the present analysis. The primary indication for EVAR was AAA transverse diameter >5 cm or a rapidly increasing sac (>1 cm yearly) if <5 cm; any symptomatic infrarenal AAA was also eligible. General contraindications for EVAR were age <18 years, allergy to contrast medium, coagulopathy, pregnancy or lactation, groin infection, life expectancy <1 year, and connective tissue disease.

Patients were included in the present analysis if they completed at least 1 year of follow-up and all relevant information was available. The study excluded data for patients with ruptured, mycotic, or inflammatory aneurysms and patients with end-stage renal disease receiving renal replacement therapy at baseline, despite eGFR levels. The institutional Ethics Committee approved the study, and all examinations were conducted in accordance with the Declaration of Helsinki (2000 Amendment).

The original prospectively assembled cohort consisted of 244 patients who fulfilled the inclusion criteria. Patients were placed in two groups according to the mode of proximal aortic fixation of the aortic stent graft that was deployed in relation to the orifice of the renal arteries: suprarenal fixation for bare suprarenal stent(s) or the infrarenal fixation mechanism. EVAR had been done with a device bearing suprarenal fixation in 72 patients and without suprarenal fixation the device in 172 patients. To include two balanced groups with the least selection bias, after the original cohort was formed, one of the investigators (P.S.), blinded to patient data apart from age, sex, AAA diameter, fixation type, and smoking history, matched patients from the suprarenal fixation group (72 cases) with individuals from the infrarenal fixation group (172 cases) for age (≤2 years), sex, AAA diameter (≤1 cm), and smoking history (never, current smoker, former smoker). A total of 46 patients from each group could be accurately matched and represented the final population of this analysis.

Study protocol. For each patient, demographics and comorbidities, including a full medical and surgical history, and full anesthetic assessment were recorded, and a full vascular examination was performed at baseline (before EVAR). All patients also underwent a computed tomography angiography (CTA) with two- or three-dimensional reconstruction before repair. Blood specimens were collected for a full blood count and routine biochemistry tests before any imaging requiring the administration of intravenous contrast. All data were prospectively entered in an electronic database before surgery once written informed consent had been obtained.

All patients were followed up according to our department's standard EVAR protocol. This included a follow-up visit at 30 days, 6 months, and 12 months after the operation, and annually thereafter. A clinical examination was performed, and routine hematology and biochemistry tests were obtained, all before imaging with intravenous contrast. Imaging included plain abdominal radiography (anteroposterior and lateral views) and a contrast-enhanced CTA at 6 months, 12 months, and annually thereafter. Data from follow-up visits, including results from blood tests, were entered in the study database.

Procedures. Indications for the deployment of a stent graft with suprarenal fixation in this series were an infrarenal aneurysmal neck <15 mm in length or a conical-shaped proximal aneurysmal neck.[22] Patients with excessive thrombus or calcification at the proximal aortic neck were not offered EVAR.

The following endovascular devices were used: Anaconda (Vascutek, Inchinnan, Scotland, UK), Gore Excluder (W. L. Gore and Associates, Flagstaff, Ariz), EndoFit tube graft (LeMaitre Vascular, Burlington, Mass), EndoFit aortouniiliac device, followed by a femorofemoral bypass (LeMaitre Vascular), Endologix Powerlink bifurcated device (Endologix, Irvine, Calif), Talent (Medtronic, Minneapolis, Minn), and Endurant (Medtronic). Indications and specifications for the implantation of each device in this center have been described in detail elsewhere.[3,8,23,24] Whenever a bifurcated endograft could be implanted, the aortouniiliac configuration was avoided because it involves an extra-anatomic bypass. The team of vascular surgeons that performed the operations selected the devices for implant according to the anatomy of the proximal and distal neck, the iliac configuration, and the amount of calcification or thrombus at each landing zone.

All procedures were performed in a fully equipped operating room with the patient under regional or general anesthesia and fluoroscopic control, by administering iopromide (Ultravist 300; Bayer Schering Pharma AG, Berlin, Germany), a nonionic contrast agent. All operations were performed by the same team of vascular surgeons and anesthetists with previous experience in EVAR using all of the devices included in the analysis.

For all patients, a standard renal protection protocol was used before the procedure, including 1.2 g of oral N-acetylcysteine (Trebon N, Uni-Pharma, Athens, Greece) administered 24 hours before EVAR. Patients with a pre-

operative serum eGFR >60 mL/min/1.73 m^2 were started on intravenous fluids (0.9% saline, 2 mL/kg/h) on the day of the operation, once they were nil by mouth. Patients with a baseline eGFR <60 mL/min/1.73 m^2 were admitted 1 day before EVAR and given intravenous normal saline (0.9% saline, 1.5 L/24 hours) for 24 hours in addition to oral fluids until nil by mouth, when they were commenced on 0.9% saline at 2 mL/kg/h. Urinary catheterization and hourly urine output measurements were routinely used during and after the procedure for at least 24 hours. Cardiac output monitoring was available in all cases through a peripheral arterial line. The administration of any contrast agent before EVAR (≤2 weeks) was avoided. Nonsteroidal anti-inflammatory drugs (NSAIDs) were stopped for at least 7 days before EVAR. Metformin was discontinued 2 days before EVAR and was not readministered until 48 hours after the procedure. No patients received bicarbonate infusion perioperatively.

Further, in accordance with our department's standard protocol for patients undergoing elective EVAR, aspirin and clopidogrel were administered the day of the procedure. Aspirin was discontinued on postoperative day 30, and clopidogrel was continued as a lifelong treatment.[25]

A plain abdominal radiograph was obtained on postoperative day 2 to assess graft integrity and position. The patient was usually ambulated on postoperative day 2 and was discharged on day 3.

Study outcomes. Assessment of renal function was based on eGFR as the primary variable of interest. eGFR was calculated from serum creatinine measurements at regular follow-up visits with the abbreviated equation of the Modification of Diet in Renal Disease (MDRD) study: eGFR (mL/min/1.73 m^2) = 186 × (serum creatinine in mg/dL)$^{-1.154}$ × (age in years)$^{-0.203}$ × (.742 if female) × (1.210 if black).[21] All patients in the study were white Caucasians. Serum creatinine was measured by a modified Jaffe method in an Abbott ARCHITECT c16000 analyzer (Abbott Diagnostics, Abbott, Park, Ill). All complications and events during follow-up were classified and reported according to the reporting standards for EVAR by Chaikof et al.[26]

Statistical analysis. Continuous parametric data are presented as mean value ± standard deviation. Categoric data are presented as absolute values and percentages. Baseline differences between the two study groups for continuous or categoric variables were evaluated with the unpaired *t*-test or the Fisher exact test, respectively. For comparisons between the baseline and the end of the study in each study group, the paired *t*-test was applied. Between-group values were compared using the unpaired *t*-test. Pearson correlation was used to assess the relation between different types of suprarenal fixation and the absolute drop in eGFR after 1 year in the suprarenal fixation group. $P < .05$ was considered statistically significant. All analyses were performed using SPSS 17.0 software (SPSS Inc, Chicago, Ill).

RESULTS

Baseline characteristics and intraprocedural events. The analysis included data for 92 patients (two women; mean age, 71 ± 7 years) who underwent EVAR of an infrarenal AAA with a mean transverse diameter of 6.1 ± 1.2 cm. Baseline characteristics of the infrarenal vs suprarenal fixation patients, which were matched in age, sex, smoking status, and AAA diameter, are summarized in Table I. The two groups did not differ significantly in history of hypertension, diabetes, hypercholesterolemia, chronic obstructive pulmonary disease, myocardial infarction, congestive heart failure, peripheral arterial disease, stroke, use of statin, and use of β-blockers. In addition, concentrations of serum urea, serum creatinine, and eGFR were also not statistically different between groups at baseline.

The anatomic characteristics of the aneurysms for both groups are summarized in Table I. Three patients in the suprarenal group had a conical neck (nine of 46 [6.53%]). The mean length of the proximal neck was 13.8 ± 0.9 mm for the suprarenal and 16.7 ± 1.9 mm for the infrarenal group ($P < .001$). None of these patients had a severely angulated proximal aneurysmal neck (>45° of angulation).

The following bifurcated devices with infrarenal proximal aortic support were deployed: Anaconda in 39 patients, Endologix Powerlink in five, and Gore Excluder in two. Devices with bare stent suprarenal proximal aortic support included the Endurant bifurcated device in 22 patients, EndoFit tubular aortic graft in 16, EndoFit aortomonoiliac device, followed by a femorofemoral bypass, in 6, and Talent bifurcated device in 2. Characteristics for each device are summarized in Table II.

The amount of contrast medium used during stent graft deployment (128 ± 36 vs 125 ± 38 mL; $P = .71$) and the duration of the procedure (107 ± 19 vs 110 ± 15 minutes; $P = .38$) were not significantly different between groups (Table I). Seven of 92 patients (8%) required a blood transfusion, all within the first 24 hours after the procedure: four (9%) in the infrarenal group and three (7%) in the suprarenal group Only two patients, both in the infrarenal group, developed hypotension during the procedure that required inotropic support. After a short stay (<24 hours) in the intensive care unit, they both made an uneventful recovery.

Procedure-related events. None of the patients died or were lost to follow-up during the 12 months. In one patient (0.72%) in the infrarenal group, the orifice of the left renal artery was unintentionally covered during deployment of an Anaconda bifurcated stent graft, but this was recognized and the device was immediately repositioned. The completion angiogram disclosed no further complications. Computed angiography showed no renal artery occlusion, dissection, or stenosis developed during follow-up. No patients required conversion to open repair during the 12-month period. In one patient (0.08%) in the infrarenal group, acute thrombosis developed in the right limb of an Anaconda bifurcated stent graft, and the patient subse-

Table I. Characteristics of the two groups at baseline evaluation and during procedure

Variable [a]	*Type of fixation*		P
	Infrarenal	*Suprarenal*	
Age, years	71 ± 7	71 ± 7	.84
Female sex	1 (2)	1 (2)	>.99
Smoking			
Current	5 (10)	5 (11)	>.99
Former	27 (59)	27 (59)	>.99
AAA diameter, cm	6.1 ± 1.2	6.2 ± 1.3	.69
Comorbidities			
Hypertension	38 (83)	40 (87)	.77
Diabetes	12 (26)	9 (20)	.62
Hypercholesterolemia	22 (49)	27 (59)	.4
COPD	3 (7)	1 (2)	.62
Myocardial infarction	6 (13)	1 (2)	.11
Congestive heart failure	1 (2)	4 (9)	.36
Stroke	0	4 (0)	.12
Peripheral vascular disease	10 (22)	14 (30)	.47
Medical therapy			
Statin use	30 (63)	35 (76)	.36
β-Blocker use	12 (26)	17 (37)	.37
Laboratory values			
Urea, mg/dL	42 ± 16	44 ± 10	.58
Creatinine, mg/dL	1.01 ± 0.33	1.08 ± 0.36	.31
eGFR, mL/min/1.73 m^2	85 ± 27	80 ± 28	.33
Hemoglobin, g/dL	13.06 ± 1.80	13.40 ± 1.71	.36
WBC, $\times 10^9$/L	8.89 ± 2.36	8.28 ± 2.35	.22
Sodium, mEq/L	140 ± 4	140 ± 5	.13
Potassium, mEq/L	4.40 ± 0.56	4.54 ± 0.59	.24
Operation time, min	110 ± 15	107 ± 19	.38
Contrast medium, mL	125 ± 38	128 ± 36	.71

AAA, Abdominal aortic aneurysm; *COPD,* chronic obstructive pulmonary disease; *eGFR,* estimated glomerular filtration rate; *WBC,* white blood cell count.
[a]Data presented are mean ± standard deviation for continuous variables and number (%) for categoric variables.

quently underwent a femorofemoral bypass to perfuse the right lower limb.

Two (2.16%) type II endoleaks occurred during follow-up in the infrarenal fixation group. Both patients were asymptomatic and remained under surveillance, and no further intervention was deemed necessary. No type I endoleaks or other device-related complications were observed during the 12-month period. All patients in both groups underwent a contrast-enhanced CTA at 6 and 12 months. Blood samples were collected before the contrast scans. Patients with type II endoleak remained under the same imaging protocol because they were asymptomatic and the aneurysms did not expand.

Renal outcomes. During the 12 months of follow-up, no patients progressed to end-stage renal disease or developed acute renal failure requiring hemodialysis. Baseline eGFR (in mL/min/1.73 m^2) was 85 ± 27 (range, 32-147) for the infrarenal group and 80 ± 28 (range, 31-152) for the suprarenal group (P = .33). Table III summarizes measures of renal function at 6 and 12 months. The serum creatinine concentration did not differ significantly between groups at 6 (P = .24) or 12 (P = .08) months after EVAR (Table III). However, in within-group comparisons, serum creatinine (in mg/dL) remained practically unchanged in the infrarenal group (from 1.01 ± 0.33 at baseline to 1.01 ± 0.37 at 6 months to 1.03 ± 0.36 at 12 months; P = .23) but was significantly increased in the suprarenal group (from 1.08 ± 0.36 at baseline to 1.10 ± 0.36 at 6 months and 1.16 ± 0.36 at 12 months; P < .001).

Evaluation of postoperative renal function with eGFR (in mL/min/1.73 m^2) showed that there were no significant differences between infrarenal and suprarenal fixation at 6 months (78 ± 24 vs 88 ± 29; P = .075) after EVAR, but patients with a suprarenal device had a significantly lower eGFR (73 ± 23 vs 84 ± 26; P = .027) at 12 months (Table III). Again, in the infrarenal group eGFR was well preserved during follow-up (from 85 ± 27 at baseline to 84 ± 26 at 12 months; P = .48) but showed a significant drop in the suprarenal group (from 80 ± 28 at baseline to 73 ± 23 at 12 months; P < .001).

We also calculated eGFR change from baseline to 6 and to 12 months for each patient. None of the patients presented a drop of eGFR of >30% at 6 or 12 months. However, this eGFR change differed significantly between the groups at 6 (P = .02) and 12 months (P < .001; Table III and Fig); on average, patients with infrarenal fixation lost 0.82 mL/min/1.73 m^2 (standard error [SE], 1.07), whereas patients with suprarenal fixation lost 6.94 mL/min/1.73 m^2 (SE, 1.43). There was no correlation between the absolute drop in eGFR after 1 year and the type of the suprarenal fixation component (P = .2, Pearson

Table II. Characteristics of the endovascular devices used in the study

Name	*Fabric*	*Type of device*	*Proximal fixation*	*1st covered stent at sealing zone*	*Aortic fixation hooks, barbs, pins*
Endurant[a]	Multi-filament polyester	2 pieces bifurcated	Suprarenal 15-mm length	2 SE nitinol M stents, 8-mm length, 2-mm internal gap	Yes on the suprarenal stent, 5 pairs fixation barbs (2 mm in length)
Talent[a]	Polyester	2 pieces bifurcated	Suprarenal 15-mm length	SE nitinol Z stent, 15 + 8 mm with overlapping = 20 mm	No
Endofit AUI[b]	PTFE, 2 layers	1-piece unibody AUI	Suprarenal 17-mm length	Independent SE nitinol Z stents encapsulated within 2 layers of PTFE	No
Endofit tube[b]	PTFE, 2 layers	Tubular aortic graft	Suprarenal 17-mm length	Independent SE nitinol Z stents; encapsulated within 2 layers of PTFE	No
Endologix Powerlink[c]	PTFE	Unibody bifurcated	Infrarenal	Unibody skeleton made from cobalt chromium interconnected alloy	No
Excluder[d]	PTFE	2 pieces bifurcated	Infrarenal	Independent asymmetric nitinol Z and M stents ~ 15 mm	Yes on the first stent, 8 pairs of 2-mm pins
Anaconda[e]	Woven polyester	3 pieces bifurcated	Infrarenal	2 independent SE nitinol fish mouth ring stents with 8-mm gap	Yes on the second stent, 4 pairs 2-mm length

AUI, Aortouniiliac; *PTFE,* polytetrafluoroethylene; *SE,* self-expanding.
[a]Medtronic, Minneapolis, Minn.
[b]LeMaitre Vascular, Burlington, Mass.
[c]Endologix, Irvine, Calif.
[d]W. L. Gore and Associates, Flagstaff, Ariz.
[e]Vascutek, Inchinnan, Scotland, UK.

Table III. Renal function outcomes and between-group comparison during follow-up

Variable	*Type of fixation*		P
	Infrarenal (Mean ± SD)	*Suprarenal (Mean ± SD)*	
Creatinine, mg/dL			
Baseline	1.01 ± 0.33	1.08 ± 0.36	.31
6 months	1.01 ± 0.37	1.10 ± 0.36	.24
12 months	1.03 ± 0.36	1.16 ± 0.36	.08
eGFR, mL/min/1.73 m^2			
Baseline	85 ± 27	80 ± 28	.33
6 months	88 ± 29	77 ± 24	.07
12 months	84 ± 26	73 ± 23	.03
eGFR change vs baseline			
6 months	2.18 ± 10.53	−3.19 ± 10.81	.02
12 months	−0.82 ± 7.30	−6.9 ± 9.72	<.001

eGFR, Estimated glomerular filtration rate; *SD,* standard deviation.

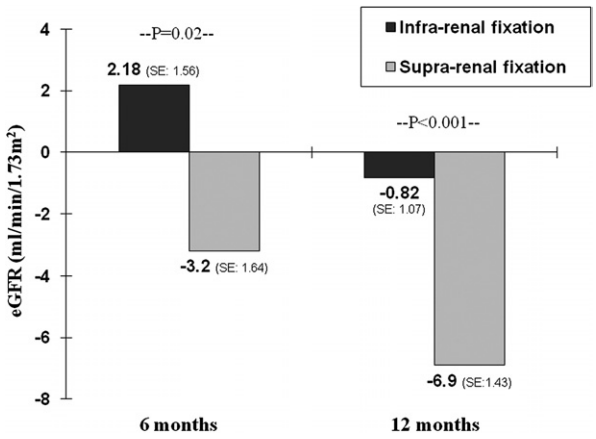

Fig. Mean (standard error [*SE*]) changes in the estimated glomerular filtration rate (*eGFR*) in the two groups are shown at 6 and 12 months of follow-up.

correlation). Patients with a lower eGFR (suprarenal group) were at increased risk of developing a higher absolute drop in eGFR after 1 year ($P < .001$, Pearson correlation).

DISCUSSION

This study was designed to examine the effects of suprarenal vs infrarenal stent graft fixation during elective EVAR of an AAA on renal function with a controlled comparison. We have carefully planned to prospectively monitor for at least 12 months all patients undergoing EVAR with infrarenal or suprarenal fixation at our tertiary center. When the prospective cohort was assembled, we blindly (for outcomes) matched patients with infrarenal or suprarenal fixation in a nested case–control design to study two balanced groups. We further used eGFR measurements based on the MDRD formula instead of only recording serum creatinine or using creatinine clearance estimations.

With this controlled and detailed evaluation, the present study showed that suprarenal graft fixation is associated with a decrease in renal function, with an average reduction of ~7 mL/min/1.73 m^2 in 12 months, whereas infrarenal fixation was associated with an average reduction of 0.8 mL/min/1.73 m^2 in the same time frame. The clear practical implication is that infrarenal fixation is not associated with a decrease in renal function above the expected average yearly loss for this population,[27,28] whereas suprarenal fixation may be associated with up to 10% loss of renal function at least in the first year. This means that end-stage renal failure will quickly develop in this patient group if the drop in renal function continues at such a rate after the first year.

Despite this loss of renal function, no renal artery stenosis, dissection, or occlusion was seen on any of the CTA imaging studies during follow-up in either group. In addition, we did not observe a significant loss of renal function in these patients. As a result, we have to hypothesize that this drop in renal function must be secondary to other factors that cannot be picked up using conventional CTA, such as microembolization into the renal vasculature,[29] during device deployment or after the procedure, due to the existence of the suprarenal fixation modalities at the orifice of the renal arteries. A recent study investigated 136 patients undergoing EVAR with infrarenal and suprarenal fixation devices to assess the rate of microembolic events using CTAs to detect perfusion defects. Eight patients (5.9%) had bilateral microembolic cortical defects, and interestingly, those with moderate or severe suprarenal or infrarenal thrombus were more likely to have renal microemboli (17% vs 0% [$P < .001$] and 9.6% vs 1.5% [$P = .08$], respectively).[30] The design and material (nitinol vs stainless steel) of the suprarenal fixation component may play a role in renal dysfunction; however, no correlation was found in our population between the absolute drop in eGFR after 1 year and the design of the suprarenal fixation component ($P = .2$, Pearson correlation).

The findings of the present study contrast with results of several authors who have published retrospective series indicating that suprarenal endograft fixation does not have a significant effect on short (<12 months) and midterm (up to 24 months) renal function,[13-18] using serum creatinine concentration or creatinine clearance (Cockroft-Gault formula) as primary end points. Two previous studies that directly compared postoperative renal function after infrarenal and suprarenal endograft fixation, based on prospectively collected data, were published by Davey et al[15] and Forbes et al[31] in 2006.

Davey et al[15] published a series of 92 patients undergoing EVAR with a suprarenal device compared with 87 patients undergoing EVAR with an infrarenal device. The study was retrospective but was based on a prospective EVAR registry. Renal function was assessed at 6, 12, and 24 months using serum creatinine and creatinine clearance. The authors mention that paired renal data were available for 135 patients with a minimum follow-up of 6 months; however, the infrarenal and suprarenal groups of the study were not matched in age, sex, smoking status, or preoperative renal function. Data at 12 and 24 months were only available for 46 and 38 patients with suprarenal fixation, respectively. Differences in serum creatinine and creatinine clearance were not significant.

Forbes et al[31] compared 59 patients in whom a Talent (infrarenal) endograft was deployed with 81 patients who received the Zenith device (suprarenal). The study was retrospective but based on a prospective registry. Mean follow-up was 5.5 months. There was no difference in the reduction in creatinine clearance between the two devices.

A systematic review of the literature in 2006[32] identified seven retrospective studies comparing suprarenal and infrarenal endograft fixation. No significant difference was found between suprarenal and infrarenal fixation with respect to renal dysfunction, but renal infarction was more common in the suprarenal fixation group (combined odds ratio, 5.189; 95% confidence interval, 3.198-8.420; $P < .001$). A meta-analysis published in 2008[33] pooled data from four retrospective studies.[13-15,18] The authors applied sophisticated statistics to adjust for study homogeneity. The pooled hazard ratio for deterioration of renal function after deploying a device with suprarenal fixation was 0.6 (95% confidence interval, 0.3-10). The authors concluded that the available data were not sufficient to accurately assess the effect of suprarenal fixation.

The present study has some limitations that need to be acknowledged. The follow-up period only extended to 12 months; thus, as in all previous studies of the field, to what extent our findings are relevant to the long-term effect of suprarenal fixation on renal function cannot be established.

Further, this study is not a randomized, controlled clinical trial randomly allocating patients to infrarenal and suprarenal graft fixation. However, given the absence of a randomized clinical trial in the field, we believe we provide the best available evidence so far, as we used a careful predefined design, including prospective recording of patient data and blind case-controlling of participants that ended in two balanced groups.

Finally, although we only matched our patients for age, sex, smoking status, and AAA transverse diameter, not many studies of this type are able to control more than two or three factors. In our case, an attempt to match for more variables would have led to a further significant decrease of the study population.

CONCLUSIONS

This study suggests for the first time that suprarenal endograft fixation in EVAR, when compared directly with infrarenal fixation, is associated with a decline in renal function at 12 months of follow-up, in contrast to previous data in the field. This finding has important implications for clinical practice because it may indicate a significant drawback of currently widely used aortic endografts with suprarenal fixation modalities. The results of this analysis clearly call for carefully designed, long-term clinical trials to shed light on this important aspect. These devices should

be rather used only in patients with challenging proximal neck anatomy that would put the fixation of the graft at risk.

AUTHOR CONTRIBUTIONS

Conception and design: AS, PS, NM, NS
Analysis and interpretation: AS, PS, JH
Data collection: AS, NM
Writing the article: AS, PS
Critical revision of the article: NS, GK
Final approval of the article: AS, PS, NM, JH, NS, DK, GK
Statistical analysis: AS
Obtained funding: AS, NS, DK, GK
Overall responsibility: AS

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Submitted Dec 2, 2011; accepted Jan 31, 2012.

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